

PATENT COOPERATION TREATY

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REC'D 05 APR 2006

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference rp/pct/04-9	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/BE2004/000111	International filing date (day/month/year) 04.08.2004	Priority date (day/month/year) 05.08.2003
International Patent Classification (IPC) or national classification and IPC INV. A61K9/52		
Applicant GALEPHAR M/F et al		
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 6 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau) a total of sheets, as follows:</i> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> <i>(sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</i>		
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application		
Date of submission of the demand 04.03.2005	Date of completion of this report 05.04.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer von Eggelkraut-Gotta Telephone No. +31 70 340-4732	



**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-18 as originally filed

Claims, Numbers

1-21 as originally filed

Drawings, Sheets

1 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-7,14,18,20,21
	No: Claims	1-4,8-12,15-17,19
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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V. Re Item V

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

- D1: WO 01/56609 A (DIERKES JUTTA ; LULEY KLAUS (DE); WESTPHAL SABINE (DE)) 9 August 2001 (2001-08-09)
- D2: DE 199 10 682 A (DIERKES JUTTA ; LULEY CLAUS (DE); WESTPHAL SABINE (DE)) 21 September 2000 (2000-09-21)
- D3: DIERKES JUTTA ET AL: "Vitamin supplementation can markedly reduce the homocysteine elevation induced by fenofibrate" ATHEROSCLEROSIS, vol. 158, no. 1, September 2001 (2001-09), pages 161-164, XP002288439 ISSN: 0021-9150
- D4: WO 03/013501 A (SERENO ANTONIO ; SMB SA LAB (BE); BAUDIER PHILIPPE (BE); VANDERBIST FR) 20 February 2003 (2003-02-20)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document):
Capsules comprising fenofibrate 200 mg, folic acid 0.65 mg, vitamin B12 0.05 mg, vitamin B6 6 mg (p. 1, l. 13 - p. 2, l. 13; p. 8, l. 5-15).
- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D2 discloses (the references in parentheses applying to this document):
A combination compositions comprising a fibrate (beza-, belco-, feno-, clofibrate) and one or more from cobalamin, folic acid, vitamin B6, betaine and N-acetylcysteine (c. 1, l. 50 - c. 2, l. 32; cl. 1,2).
- 2.3 Claim 1 tries to define the composition in terms of a result to be achieved by specifying

in that the second composition comprising a homocysteine lowering agent shall be in a modified release form. This result to be achieved can not serve as a distinguishing technical feature vis à vis the prior art.

Furthermore, the terms "first composition" and "second composition" do not distinguish the claimed subject-matter from the state of art D1 and D2, as set out under points 2.1 and 2.3.

3 DEPENDENT CLAIMS 2-21

Dependent claims 2-21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). Document D3 discloses a treatment involving the administration of micronized fenofibrate (200 mg /day) and a vitamin supplement comprising folic acid (0.65 mg), vitamin B12 and vitamin B6 (D3, abstract; p. 162, left hand col, l. 6-10; p. 163, par.1). Document D4 discloses capsules comprising fenofibrate and polyglycerides (Gelucire 44/14) (D4, p. 5, l. 13-26; examples).

VIII. Re Item VIII

Certain observations on the international application

4 The term "homocysteine lowering agent" being an essential feature of the invention encompasses potentially a great number of compounds that cannot be identified without undue burden. However, the present application provides support for only a few compounds, namely folic acid, vitamin B12, vitamin B6 and betaine. Consequently, claims 1,17 and 22 lack clarity and support according to Art. 6 PCT.

4.1 Plasma levels vary individually as a function of the patient tested. Therefore parameters directed to the plasma level or absorption profile to be achieved by the administration of a medicament can not form a basis for a claim fulfilling the requirements of Article 6 PCT with respect to clarity. Claim 15 does therefore not fulfill the requirements of Article 6 PCT.

4.2 Claim 16 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-

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matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.